

Diagnostic Use of Lung Ultrasound for Suspected Pneumonia in Nepal

NCT02949141

May 16, 2016

CONSENT TO PARTICIPATE IN RESEARCH

You are invited to participate in a research study conducted by doctors in the Patan Emergency Department. Your participation in this study is entirely voluntary. You should read the information below and ask questions about anything you do not understand, before deciding whether or not to participate. If you don't want to participate in the study, you will still get the standard treatment.

• PURPOSE OF THE STUDY

The purpose of this study is to help us determine if lung ultrasound is useful for the diagnosis of pneumonia. As an easy-to-use, portable, and relatively cheap test to use throughout Nepal for the diagnosis of pneumonia, especially in areas with limited access to X-rays.

• PROCEDURES

If you volunteer to participate in this study, we will do the following free of charge:

1. Record your symptoms on a data form.
2. Perform a bedside lung ultrasound test to evaluate for possible pneumonia.
3. Have you get a chest CT scan to confirm whether you have pneumonia or not.

• POTENTIAL RISKS AND DISCOMFORTS

You will be exposed to small dose of radiation related to getting a CT scan. The risk of the radiation from one CT scan leading to cancer in your lifetime is 1 in 2000, much smaller than the risk of a person naturally getting cancer. Also, we will inform you of any other findings on the CT scan. In those cases, you will be responsible for any further testing or follow-up that is recommended.

There is no risk related to the ultrasound test. Additionally, there is risk to loss of privacy related to collecting your test results, but all precautions will be taken to make sure these are kept de-identified and locked in an office or on a password protected computer.

• POTENTIAL BENEFITS TO SUBJECTS AND/OR TO SOCIETY

You are likely to benefit from the high quality diagnostic test that is being performed will give a more thorough evaluation of your condition. Additionally, this study will likely provide another diagnostic test that will help in the diagnosis of patients presenting with symptoms of pneumonia. The results of this study will help patients in the future at this hospital and likely in other parts of the world. The results from this study will benefit the scientific community as a whole.

• COMPENSATION FOR PARTICIPATION

You will not receive any payment or other compensation for participation in this study. There is also no cost to you for participation.

- **CONFIDENTIALITY**

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. All of our data will be kept in a locked file cabinet in a locked office. Additionally, any data on the computer will be kept password protected. All data collected will be de-identified and a code number will be assigned to each participant.

- **PARTICIPATION AND WITHDRAWAL**

You can choose whether or not to be in this study. If you volunteer to be in this study, you may withdraw at any time without consequences of any kind. You may also refuse to answer any questions you do not want to answer. There is no penalty if you withdraw from the study and you will not lose any benefits to which you are otherwise entitled.

- **IDENTIFICATION OF INVESTIGATORS**

If you have any questions or concerns about the research, please feel free to contact:

- **RIGHTS OF RESEARCH SUBJECTS**

The Patan Review Board has reviewed my request to conduct this project. If you have any concerns about your rights in this study, please contact one of us listed above.

I understand the procedures described above. My questions have been answered to my satisfaction, and I agree to participate in this study. I have been given a copy of this form.

Printed Name of Subject

Signature of Subject

Date

Signature of Witness

Date